

RESPONSE TO OFFICE ACTION  
DATED AUGUST 10, 2004

Appln. No. 09/998,880

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December 14, 2004

**REMARKS**

This is in response to the Office Action dated August 10, 2004. Reconsideration is respectfully requested.

Request for Extension of Time

Applicants respectfully request that the period for reply be extended two months, from November 10, 2004 to January 10, 2005. Enclosed is Form PTO-2038 authorizing the charge \$225 in payment of the two-month extension fee pursuant to 37 CFR 1.17(a)(2).

Summary of the Rejections

Claims 1-19 are pending. All claims are rejected under 35 USC 112, first paragraph, due to the scope of terms of relation in the claims which the Examiner believes are not reasonably enabled by the specification. The claims are further rejected under 35 USC 112, second paragraph, for use of what the Examiner considers subjective terms uncertain as to meaning and scope.

Claims 1-3, 5-9, 18 and 19 are rejected as anticipated by U.S. Patent No. 5,718,159 to Thompson. Claims 4 and 17 are rejected as obvious over Thompson in view of U.S. Patent No. 6,534,084 to Vyakarnam et al. Claims 1-3 are rejected as anticipated by U.S. Patent No. 5,891,191 to Stinson. Claims 5-9, 18 and 19 are rejected as obvious over Stinson in view of Thompson. Claims 4 and 17 are rejected as obvious over Stinson in view of Vyakarnam et al.

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Summary of the Invention

Applicants' invention concerns a supported lattice for cultivating living cell tissue. The device comprises a support substrate formed of resilient filamentary members interlaced so as to create relatively large interstices across which cells cannot grow. A cell cultivation lattice is interlaced with the support substrate. The cell cultivation lattice is formed of flexible filamentary members interlaced so as to form smaller interstices that will support the cells so that they form a substantially continuous surface of living tissue across the larger interstices of the support lattice.

The supported lattices are preferably tubular in shape and can comprises two coaxial tubular lattices that have cell cultivation lattices of different sizes on their inner and outer diameters which promote the growth of different types of cells on the inner and outer portions of the device.

Enablement and Indefiniteness Rejections

Applicants have amended the claims to substantially eliminate terms of relation which the Examiner finds ambiguous. Applicants have also defined the relative sizes of the interstices as they are described in the specification substantially as suggested by the Examiner so as to obviate any question of enablement.

With respect to the confusion perceived by the Examiner regarding Claim 11, applicants have amended the claim to indicate that, for a supported lattice comprising two coaxial tubes, each having their own support substrate and cultivation lattice, the size of the interstices on one of the cultivation lattices is different from the size of the interstices on the other cultivation lattice. As noted on page 15, lines 1-12, this provides a structure having an outer cultivation lattice

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of one size and an inner cultivation lattice having a different size.

Applicant has also amended Claims 14 and 15 to reflect the Examiner's concerns respecting enablement.

The Argument

Applicants respectfully traverse the rejections as to anticipation and obviousness as explained in the arguments presented below on a claim-by-claim basis.

Claim 1

Claim 1 is rejected as anticipated by Thompson. However, as implicitly admitted by the Examiner, there is no teaching in Thompson of a lattice having interstices sized specifically to cultivate living cells. Column 8, lines 10-15, of Thompson teach that the layers comprising the prosthesis are impervious to blood and other bodily fluids. Furthermore, the examples provided in columns 11 and 12 teach "water permeability comparable to that of a vascular graft" (column 12, lines 64-65), i.e., no permeability so that the prosthesis is substantially fluid tight. Finally, column 14, lines 34-38, emphasize that the prosthesis according to Thompson achieves "the impermeability associated with vascular grafts".

This characteristic of impermeability is not advantageous for the promotion of cell growth, wherein permeability is desired so that fluids and gases can reach the cells. The Examiner's contention that "the sheet or fabric of the prosthesis is inherently capable of functioning for cultivating cells to form tissue" is made without substantiation and contrary to the express teachings of the cited reference which continuously emphasizes the fluid tight aspect of the prosthesis. Applicants contend that Thompson cannot properly support a rejection on the basis of

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anticipation because it fails to teach a supported lattice having interstices sized to support the growth of cells in a two dimensional array as recited in Claim 1. The requirement for anticipation is that the cited reference must teach every element of the claim. "Every element of the claimed invention must be literally present, arranged as in the claim."

Richardson v. Suzuki Motor Co., 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989).

Claim 1 is also rejected as anticipated by Stinson on substantially the same basis as Thompson. Again, however, Stinson emphasizes the impermeability of the prosthesis (column 6, lines 52-58; column 7, lines 1-2 and lines 50-55). The Examiner is ignoring the significant differences between the express teaching of Stinson and the features recited in the claim that specifies interstices sized to support cell growth. There is no such teaching or suggestion in Stinson, and therefore, this reference does not properly support the rejection on the basis of anticipation, which requires that all claim elements be taught. "The identical invention must be shown in as complete detail as is contained in the patent claim." (Id. at 1920).

Claims 2-19 depend, either directly or indirectly, on Claim 1 and should be allowable for the same reasons that Claim 1 is allowable over the cited references Thompson and Stinson.

Claims 4 and 17

Claims 4 and 17 are rejected as obvious over Thompson in view of Vyakarnam et al. As admitted by the Examiner, Vyakarnam et al discloses a polymer foam. The Examiner further states that it would be obvious to provide the foam between the structural strands of Thompson.

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Applicants' dispute this assertion by the Examiner, contending that it would not be obvious to combine the foam disclosed in Vyakarnam et al with the structural strands of Thompson, and even if this were done, the resultant device would not yield applicants' invention.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference or references when combined, must teach or suggest all the claim limitations. The cited references Thompson and Vyakarnam et al fail to meet two of these three requirements and, thus, cannot properly support the rejection of applicants' claims on the basis of obviousness.

Contrary to the Examiner's position, there is no motivation to provide the porous sheeting of Vyakarnam et al between the structural strands of Thompson. Thompson discloses a graft that is used to repair a vascular aneurysm and, therefore, has low permeability so as to be fluid tight (see column 8, lines 10-15; column 12, lines 64-65; and column 14, lines 34-38 as noted above). Incorporating porous sheeting as proposed would render the Thompson graft porous and unsuited for its intended purpose as a graft for the repair of an aneurysm because such a graft must remain fluid tight to be effective and relieve the fluid pressure from the weakened section of the vascular vessel. It is well established precedent that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 221 USPQ 1125 (Fed. Cir. 1984). Clearly, the modification of

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Thompson proposed by the Examiner would render Thompson unsatisfactory as a graft for the repair of a vascular aneurysm, and therefore, there is not motivation for such a modification.

Furthermore, even if the modification proposed by the Examiner were made, it would not yield applicants' invention as recited in the claims. Claims 4 and 17 depend on Claim 1 which recites a supported lattice comprising a support substrate of interlaced filamentary members and a cell cultivation lattice of interlaced filamentary members. Nowhere does this claim recite a support lattice combined with porous foam sheet as results from the Examiner's proposed modification. Establishment of the prima facie case requires that the prior art reference or references when combined, teach or suggest all the claim limitations. Clearly, the proposed modification fails to meet this requirement because it does not teach the structure recited in the claims.

These same arguments apply against the rejection of Claims 4 and 17 as obvious over Stinson in view of Vyakarnam et al. These references also fail to meet the criteria necessary to establish a prima facie case of obviousness because there is no motivation, and even when combined, the references fail to teach all of the claim limitations.

Claims 10-16

Applicants note that Claims 10-16 are not disclosed in the prior art, as mentioned by the Examiner.

Summary

Applicants have amended the claims so as to address the Examiner's concerns respecting enablement and indefiniteness. Applicants have further presented arguments showing that the cited references do not support the rejection of the claims on

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the basis of anticipation or obviousness. Applicants believe that the application is in condition for allowance and respectfully request that it be passed to issue.

Respectfully submitted,

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Enclosure

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